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APPLICATION NO.	FILING DATE	INVENTOR NAME(S)	ATTORNEY, PROSECUTOR	AGENT MAILING NO.
09/667,365	09/21/2000	Misaka Sugimura	LEWIS ROYCE	9072

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EXAMINER

PAWLINGS STEPHEN E

CLASS. OFF. ACTION

DATE MAILED: 12/31/2000

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Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/667,365

Applicant(s)

SUGANUMA ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2002 and 23 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) 1-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 81-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 4) ☐ Interview Summary (PTO-413) Paper No. _____

DETAILED ACTION

1. Applicants' election in Paper Nos. 12 and 14 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-86 are pending in the application. Claims 1-80 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.
3. Claims 81-86 are currently under prosecution.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 81-86 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The teachings of the specification cannot be extrapolated to the enablement of the claimed invention because the amount of guidance, direction, and exemplification provided are insufficient to enable the skilled artisan to have a reasonable expectation of successfully using the claimed invention. Factors to be considered in determining

whether the specification, taken as a whole, enables the nature of the invention are: (1) the state of the art, the relative skill of those in the art, the amount of direction or guidance disclosed in

the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are drawn to a method for screening compounds to identify compounds that inhibit or abrogate the G2 cell cycle arrest checkpoint, wherein said method comprises contacting a cell with a polypeptide comprising SEQ ID NO: 1897 and wherein said polypeptide acts as a G2-checkpoint-inhibiting positive control. The specification teaches that a polypeptide that inhibits or abrogates the G2 checkpoint must be a substrate for, or be phosphorylated by Chk2 kinase (pages 44-46, Example 2). The specification teaches that peptides were synthesized and tested for the ability to act as substrates of Chk2 kinase; the results of the analyses are disclosed in Table 1 on pages 46-99. The specification teaches that the peptides of SEQ ID NO: 12 and SEQ ID NO: 971 were found to be the best substrates of Chk2 kinase in the assays. Additionally, according to the disclosure, peptides of SEQ ID NOs: 1 and 1906-1921 were found to be phosphorylated by Chk2 kinase (page 45); however, for example, peptides of SEQ ID NOs: 3-9, 14-21, 26-29, 110-370, 377-635, 657-897, and still many other peptides tested, were not substrates for the kinase. Anyone peptide that is not a substrate for the kinase cannot be reasonably expected to act as the positive control to which the claims refer.

The specification apparently does not disclose whether the peptide of SEQ ID NO: 1897, or any other polypeptide comprising SEQ ID NO: 1897 is capable of acting as a substrate of Chk2. Because the specification does not apparently provide guidance supporting the assertion that a polypeptide of SEQ ID NO: 1897 would be expected to act as a substrate of Chk2, the skilled artisan could not use the claimed invention with a reasonable expectation of success without first having to determine if a polypeptide comprising SEQ ID NO: 1897 can be used as a positive control, or is, in

inhibiting or abrogating the G2 checkpoint and in view of the lack of guidance and direction that would instruct the artisan to know whether a polypeptide comprising SEQ

ID NO: 1897 should be expected to be a substrate of Chk2, the skilled artisan could not predict whether a polypeptide comprising SEQ ID NO: 1897 should be reasonably expected to act as a substrate of Chk2. Without knowledge of the certainty or probability that a polypeptide comprising SEQ ID NO: 1897 is a substrate of Chk2 kinase, the skilled artisan could not have a reasonable expectation of success in practicing the claimed invention without the need to perform additional, undue experimentation.

Conclusion

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

